DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

February 22, 2000

Sidney M. Wolfe, M.D.
Director
Public Citizen Health Research Group
1600 20th Street N.W.
Washington, DC 20009-1001

Dear Dr. Wolfe:

Thank you for your letter of February 3, urging the Food and Drug Administration (FDA) to immediately revoke those parts of the final rule on structure/function claims for dietary supplements that classify as non-diseases morning sickness and edema of pregnancy.

In the final rule, FDA announced that it would not treat as diseases common conditions associated with natural states or processes that do not cause significant or permanent harm and that claims about beneficial effects on such conditions would not be treated as disease claims. FDA stated that claims about common, mild conditions related to pregnancy, such as morning sickness and leg edema, would be considered structure/function claims.

After we published the final rule, we received additional comments such as yours that raised concerns about the safety of dietary supplement use during pregnancy. As a result, on February 9, we issued a statement that advised dietary supplement manufacturers not to make any claims related to pregnancy on their products until additional guidance is issued. The Agency has placed on public display a Federal Register notice announcing that it is holding a public meeting on March 30, in the Crystal Ballroom of the Gaithersburg Hilton to discuss safety issues associated with dietary supplement use during pregnancy. You are certainly encouraged to attend this public meeting. If you wish to speak during the meeting, you will need to file a notice of participation by March 17. The notice of participation form, which can be submitted electronically, will be available at the following web site: http://www.fda.gov/cder/calendar/meeting/pregsup2000/default.htm. This site will also contain a copy of the Federal Register notice, questions to be addressed, and other relevant information.

Once again, thank you for your comments and concerns.

Sincerely,

Jane E. Henney, M.D.
Commissioner of Food and Drugs

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